K002599

SEP 21 2000

AcryMed

510(k) Summary

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Contact Person: Dr. Bruce L. Gibbins, Chairman & CTO
Date of preparation: August 16, 2000
Device Name (proprietary): AcryDerm Silver Antimicrobial Wound Dressing
Common Name: Moist wound dressing
Classification Name: Hydrophilic wound dressing
Classification: Unclassified
Legally marketed device(s) for substantial equivalence comparison:
AcryDerm Silver Antimicrobial Barrier Dressing, (AcryMed, Inc.)
Acticoat Silver Coated Dressing, (Westaim Biomedical Inc., NH)
Acticoat Composite Wound Dressing, (Westaim Biomedical Inc., NH)

Description of Device: AcryDerm Silver Antimicrobial Wound Dressing is a moist sheet wound dressing that contains silver halide that may help to reduce growth of microbial contaminants of the dressing. The base matrix is composed of a hydrophilic polyacrylate absorbent sheet containing silver halide and stabilizers. AcryDerm Silver Antimicrobial Wound Dressing will be supplied as sterile sheets of 2x2"; 2x4"; 4x4"; 4x8"; of 8x8" sizes, packaged in single use heat sealed medical grade foil pouches. The single use primaries will be packed, with a product insert, as 10 primaries per intermediate dispenser chipboard carton, and 5 intermediate cartons per case. Biocompatibility has been assessed according to Part-1 of the ISO standard (*Biological Evaluation of Medical Devices*).

Intended Use of the Device: AcryDerm Silver Antimicrobial Wound Dressing is intended for use on partial and full thickness external wounds such as pressure sores, arterial ulcers, diabetic ulcers, and venous stasis ulcers and on acute wounds such as draining surgical wounds, lacerations, donor site, and exudating first and second degree burns, and abrasions. AcryDerm Silver may be used over debrided and grafted partial thickness wounds.

Technological Characteristics: AcryDerm Silver Antimicrobial Wound Dressing is a sterile, single use unsupported synthetic absorbent polyacrylate hydrogel containing silver halide and stabilizers. The product carries the general classification name, "Hydrophilic wound dressing". The composition of AcryDerm Silver Antimicrobial Wound Dressing is identical to the predicate device, AcryDerm Silver Antimicrobial Barrier Wound Dressing. AcryDerm Silver contains silver that may control microbial contamination of the dressing similar to the silver in Acticoat Silver Coated Dressing and Acticoat Composite Dressing (Westaim Biomedical).

Manufacturing: AcryDerm Silver Antimicrobial Wound Dressing will be manufactured according to the product specifications and under good manufacturing practices that ensure the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 21 2000

Bruce Gibbins, Ph.D.
Chief Technology Officer
AcryMed, Inc.
12232 SW Garden Place
Portland, Oregon 97223

Re: K002599
Trade Name: Silver Antimicrobial Wound Dressing
Regulatory Class: Unclassified
Product Code: KMF
Dated: August 16, 2000
Received: August 21, 2000

Dear Dr. Gibbins:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Vochmer

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K002599

DEVICE NAME: AcryDerm Silver Antimicrobial Wound Dressing

INDICATIONS FOR USE:

AcryDerm Silver Antimicrobial Dressing is an effective barrier to bacterial penetration. The barrier function of the dressing may help reduce infection in partial and full thickness wounds including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, abrasions and lacerations, donor sites and surgical wounds. AcryDerm Silver may be used over debrided and grafted partial thickness wounds.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAG
IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Portnoy

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K002599

Prescription Use X OR Over-The-Counter-Us
(Per 21 CFR 801.109) (Optional Format